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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/611,257	07/06/2000	Terrance P. Snutch	381092000721	5449

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EXAMINER
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ART UNIT	PAPER NUMBER
1646	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/611,257	Applicant(s) Snutch et al
	Examiner Nirmal S. Basi	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 12, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above, claim(s) *7-13 and 15-17* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-6 and 14* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *5 and 7*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Amendment and response to restriction filed 1/11/02 (paper number 8) and Response to a communication filed 5/21/02 (paper number 10) have been entered.

2. Applicant's election with traverse of Group I, drawn to α_{1G}, claims 1-6 and 14, in Paper No. 10, is acknowledged. The traversal is on the ground(s) that the there are unifying structural features with respect to α_{1G}, α_{1H}, and α_{1I} since all constitute genes encoding the same type of calcium ion channel. Applicants arguments have been fully considered but not found persuasive. The calcium-ion channels, α_{1G}, α_{1H}, and α_{1I}, are all functionally and structurally different compound capable of separate use and manufacture. There are no disclosed conserved regions which are critical to the structure and function of the genus claimed. The restriction is maintained for reasons of record.

The requirement is still deemed proper and is therefore made FINAL.

3. The drawings objected to because each Figure must be labeled separately and described separately in the Brief Description of the Drawings. For example: a) Figure 6 should be labeled as Figure 6A and 6B, 6C, 6D and 6E and described separately in the Brief Description of the Drawings as Figure 6A and 6B, 6C, 6D and 6E, or the equivalent, as required by 37 C.F.R. § 1.84 (u)(1). Appropriate correction is required.

4. ***Sequence Rules Compliance***

4. This application fails to comply with the sequence rules, 37 CFR 1.821-1.825. Nucleotide and polypeptide sequences must be identified with the corresponding SEQ ID NO. Title

37, Code of Federal Regulations, Section 1.821 states "reference must be made to the sequence by use of the assigned identifier", the identifier being SEQ ID NO. Sequences in Figures 6 and 8 must be identified by their corresponding SEQ ID NO:. Polypeptide sequences on page 7 must be identified by SEQ ID NO:.

Specification

5. Acknowledgment is made of applicant's claim for priority. It is noted, however, that the priority information on page 1 of the specification is not correct with respect to application No. 09/030,428. It appears application No. 09/030,428 should be application No. 09/030,482. Application as required to provide the correct application to which priority is claimed.

Appropriate correction is required.

Claim Rejection, 35 U.S.C. 112

6. Claims 1-6 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2 and 14 are indefinite because the name "α_1 subunit of a mammalian T-type calcium channel" has not been defined in the claims and specification so as to allow the metes and bounds of the claims to be determined. The specification discloses, the T-type α_1 subunit molecules are defined by homology to human and rat nucleotide and amino acid sequences, SEQ

ID NOs: 23-28, and the T-type α_1 subunits will have typically at least 50% homology to said amino acid sequences. The description of T-type α_1 or T-type α_{1G} does not provide a meaningful structural limitation to the claimed T-type α_{1G}. There are millions of possibilities to the structure. The terms "α_1 subunit" and " α_{1G} subunit" has been defined only in general functional terms and lacks structural information so as to allow the metes and bounds of the claim to be determined. It is not clear which DNA sequences would be considered "α_{1G} subunit" or α_{1G} subunit. Therefore, name α_1 subunit and α_{1G} subunit of a mammalian T-type calcium channel does not sufficiently serve to characterize said subunit. It is suggested, to overcome the rejection, the claims be amended to refer to SEQ ID NO:.

Further claim 6 is indefinite because it is unclear what interaction is a functional calcium channel so as to allow the metes and bounds of the claim to be determined.

Claim 3 is indefinite because it is not clear what is meant by"derived" so as to allow the metes and bounds of the claim to be determined. Does derived mean it a natural molecule or has the molecule been mutated to a non-natural molecule,

Claim 14 is indefinite because it is not clear what is an "oligonucleotide which consists essentially of a nucleotide sequence of a T-type calcium channel α1 subunit" so as to allow the metes and bounds of the claim to be determined. Since it is not clear what is a T-type calcium channel α1 subunit, for reasons given above, it follows it is not clear what is an "oligonucleotide which consists essentially of a nucleotide sequence of a T-type calcium channel α1.

Claims 2, 4-6 are rejected for depending on an indefinite base claim and fail to resolve the issues raised above.

Claim Rejections - 35 USC § 101 and 35 USC § 112, 1st paragraph

The following is a quotation of 35 U.S.C. 101:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-6 and 14 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

A "specific utility" is a utility that is specific to the subject matter claimed, as opposed to a "general utility" that would be applicable to the broad class of the invention. A "substantial utility" is a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. A "well established utility" is a utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with

the knowledge of one skilled in the art. A "well established utility" must also be specific and substantial as well as credible.

Based on the record, there is not a "well established utility" for the claimed invention.

Applicant has asserted utilities for the "α_1 subunit of a mammalian T-type calcium channel". For example, the specification at page 1 asserts that, "The present invention relates to T-type channel encoding sequences, to the expression of these sequences, and methods to screen for compounds which antagonize calcium channel activity". Further the specification discloses the calcium channels can be used to evaluate the effects of pharmaceuticals and /or toxic substances and the identified compounds used to treat conditions associated with undesirable calcium channel activity. Some of the conditions include, epilepsy, sleep disorders, mood disorders, cardiac hypertrophy, arrhythmia and hypertension (page 5). The present invention, provides sequences for novel mammalian calcium channel subunits of T-type calcium channels, which are labeled as α_{1G}, α_{1H} and α_{1I} subunits". The specification discloses these subunits, either alone or assembled with other proteins, can produce functional calcium channels, which can be evaluated in model cell lines to determine the properties of the channels containing the subunits of the invention. Theses cell lines can be used to evaluate the effects of pharmaceuticals and /or toxic substances on calcium channels incorporating α_{1G}, α_{1H} and α_{1I} subunits. The specification discloses polynucleotide encoding "α_1 subunit" may be useful as probes in screening human cDNA libraries for genes encoding these novel calcium channel subunits, the α_1 subunit may be

used to generate antibodies, cell lines expressing α_1 subunit may be used to evaluate compounds as pharmacological modifiers of the function of novel calcium channel subunits.

The utilities asserted by Applicant are not substantial or specific. Neither the specification nor the art of record disclose any disease states treatable by the novel polynucleotides, of instant invention, or polypeptides encoded by them. Although the DNA of SEQ ID NO:23 encodes a channel protein (α_{1G} subunit) which transports calcium, neither the specification nor the art of record disclose any instances where blocking any effects of said channel protein encoded by the DNA of SEQ ID NO:23 reduces the effect of a disease state. Thus the corresponding asserted utilities are essentially methods of treating unspecified, undisclosed diseases or conditions, which does not define a "real world" context of use. Treating an unspecified, undisclosed disease or condition would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use especially when the complete sequence of the claimed invention is not known. Since neither the specification nor the art of record disclose any activities or properties that would constitute a "real world" context of use for the disclosed polynucleotides or the polypeptides encoded by them, further experimentation is necessary to attribute a utility to the claimed polynucleotides and encoded polypeptides. See Brenner v. Manson, 383 U.S. 519, 535–36, 148 USPQ 689, 696 (1966) (noting that "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing", and stated, in context of the

utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."). Since the utilities asserted by Applicant for polynucleotide and polypeptide of instant application are not substantial or specific, then it follows that the method of claim 6, also has no utility.

8. Claims 1-6 and 14 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Further, even if one of skill in the art were enabled to use the instant method, one would not be enabled to practice the method as broadly claimed because the general structural attributes definitive of α_1-subunit and α_{1G}-subunit for T-type calcium channels are not taught in the specification, nor known in the art (also see rejection under 35 U.S.C. 112, second paragraph above). One would be enabled to make T-type channels using only the instant α_{1G} or α_1 subunits. Further the names encompass non-functional proteins encoded by claimed DNA. Applicant has not shown how to use said non-functional ion channels.

9. Claims 1-6 and 14 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

possession of the claimed invention. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

Claims 1-6 and 14 are directed to DNA encoding calcium channels of T-type α_1 or T-type α_{1G}. The DNA is identified only by name.

The specification discloses rat cDNA of SEQ ID NO:23 encode the T-type α_{1G}. The specification discloses, the T-type α_1 subunit molecules are defined by homology to human and rat nucleotide and amino acid sequences, SEQ ID NOs: 23-28, and the T-type α_1 subunits will have typically at least 50% homology to said amino acid sequences. The description of T-type α_1 or T-type α_{1G} does not provide a meaningful structural limitation to the claimed T-type α_{1G}. There are millions of possibilities to the structure. The terms "α_1 subunit" and " α_{1G} subunit" has been defined only in general functional terms and lacks structural information so as to allow the metes and bounds of the claim to be determined. It is not clear which DNA sequences would be considered "α_{1G} subunit" or α_{1G} subunit and encode functional channels. These subunits are believed to represent two new types of α_1 subunits of human voltage-dependent calcium channels The DNA molecules encompassed by the claims correspond to such a structurally diverse genus, as defined by the specification with no disclosure of the regions critical to function. The claims, as written, however, encompass polynucleotides which vary substantially in length and also in

nucleotide composition. The broadly claimed genus encompasses functional calcium ion channel polypeptides encoded by claimed DNA, as non-functional channels as well as chimeric constructs and variants.

The instant disclosure of a single species of nucleic acid does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length genes. A description of a genus of DNAs may be achieved by means of a recitation of a representative number of DNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polynucleotides. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. The specification proposes to discover other members of the genus by using hybridization techniques. There is no description, however, of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polynucleotides encompassed and no identifying characteristic or property

of the instant polynucleotides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of specific nucleotide sequences and the ability to screen, is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

An adequate written description of a DNA, such as the cDNA of instant application, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606. (page 1404)

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
August 12, 2002

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